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Pre-Conf as a Data Review Layer:
An AbbVie Case Study for Optimized Clinical Data Flow

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ABSTRACT

AbbVie's Pre-Conformance (Pre-Conf) data review layer revolutionizes clinical trial data management by harnessing advanced machine learning and artificial intelligence. This solution ensures rapid standardization and validation of diverse clinical data domains, bridging the gap between raw data collection and formal regulatory conformance. Pre-Conf's accelerated deployment enables robust, automated edit checks, customizable views, and real-time monitoring, reducing timelines and ensuring high-quality submission-ready datasets. The case study demonstrates enhanced efficiency, compliance, and data transparency for clinical trials, supporting patient safety and regulatory success.

INTRODUCTION

Modern clinical trials are becoming increasingly complex, driven by the proliferation of data sources such as eCRFs, laboratory results, wearables, and mobile apps. This diversity presents challenges in data integration, quality control, and timely regulatory submission. AbbVie addresses these challenges by implementing a Pre-Conformance layer, a transformative approach combining machine learning models, AI-driven edit checks, and expert feedback. This layer acts as an intermediary in the data flow, standardizing and reviewing clinical data before SDTM conformance. The goal is to deliver cleaner datasets, minimize errors, and streamline trial timelines from EDC go-live to submission.

CLINICAL DATA FLOW

The optimized clinical data flow at AbbVie is structured around several sequential stages:

1. Data Acquisition: Patient data is collected via Electronic Data Capture (EDC) systems, files, labs, devices, and wearables. The data comes in heterogeneous formats requiring consolidation.
2. Pre-Conformance Review: Pre-Conf layer is initiated typically within two weeks of EDC go-live. AI and ML models predict source-to-target mappings (from raw attributes to CDISC SDTM standards), leveraging prior mapping knowledge and expert input
3. Quality Assurance: Automated deterministic and AI-based edit checks are applied, identifying anomalies, outliers, protocol deviations, and missing values. The system also tracks patient data quality in real time, with interactive dashboards that provide holistic patient views.
4. Reviewer Enablement: Customizable listings and study-specific data views enable reviewers to rapidly assess data quality, highlight issues, and accelerate resolution.
5. Downstream Processing: Fully standardized and reviewed datasets are transferred for statistical analysis (Aspen, SCE), adjudication, and regulatory submission, supporting safety analysis and compliance.

PRE-CONFORMANCE LAYER

The pre-Conf layer is the cornerstone of AbbVie's data review strategy:

- Machine Learning-Driven Mapping: Models use historical mapping data and expert feedback to predict how raw attributes should be standardized (CDISC SDTM), reducing manual mapping time and errors.
- Automated Edit Checks: Both deterministic (rule-based) and AI (pattern-based) checks flag data inconsistencies, protocol violations, and missing data. This approach increases detection accuracy and speed.
- Customizable Listings & Dashboards: Pre-Conf generates interactive patient profiles, dashboards, and listing views tailored for individual studies or roles (e.g., adjudicators, statisticians).

- Real-Time Monitoring: The system continuously tracks patient data quality, allowing for immediate issue resolution and proactive compliance assurance.
- Expert Feedback Loop: Human experts review flagged mapping suggestions and edit checks, refining model accuracy and ensuring transformations meet regulatory and study standards.
- Submission-Readiness: Only datasets passing rigorous conformance checks are forwarded, minimizing downstream errors and decreasing regulatory review cycles.

CONCLUSION

AbbVie's Pre-Conf data review exemplifies the power of integrating technology and expertise in clinical trial data management. The real-time standardization, automated anomaly detection, and customizable review tools support faster study execution, cleaner data, and improved regulatory compliance. By leveraging AI, machine learning, and expert input, AbbVie has built a scalable, efficient data pipeline that supports patient safety and expedites regulatory approval, setting a benchmark for modern clinical data infrastructure.